

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year)

14 September 2000 (14.09.00)

International application No.

PCT/US99/30503

Applicant's or agent's file reference

B0192/7011WO

International filing date (day/month/year)

21 December 1999 (21.12.99)

Priority date (day/month/year)

22 December 1998 (22.12.98)

Applicant

GORDON, Robert, Douglas et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

24 May 2000 (24.05.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Manu Berrod

Telephone No.: (41-22) 338.83.38

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

BALDOCK, Sharon Claire
BOULT WADE TENNANT
Verulam Gardens
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GRANDE BRETAGNE

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24/12/98
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**NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)**

Date of mailing
(day/month/year)

19.04.2001

Applicant's or agent's file reference
SCB/51935/004

IMPORTANT NOTIFICATION

International application No.
PCT/US99/30503

International filing date (day/month/year)
21/12/1999

Priority date (day/month/year)
22/12/1998

Applicant

JANSSEN PHARMACEUTICA N.V. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

RECEIVED

23 APR 2001

Name and mailing address of the IPEA/

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BOULT WADE TENNANT





PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| | | | |
|---|---|--|--|
| Applicant's or agent's file reference SCB/51935/004 | | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) | |
| International application No. PCT/US99/30503 | International filing date (day/month/year) 21/12/1999 | Priority date (day/month/year) 22/12/1998 | |
| International Patent Classification (IPC) or national classification and IPC C12N15/12 | | | |
| Applicant JANSSEN PHARMACEUTICA N.V. et al. | | | |
| <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p> | | | |
| <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input checked="" type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input checked="" type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application | | | |
| Date of submission of the demand 24/05/2000 | | Date of completion of this report 19.04.2001 | |
| Name and mailing address of the International preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tlx 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized officer Heckl, K Telephone No. +49 89 2399 8430  | |

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/US99/30503

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17):*)
Description, pages:

1-55 as originally filed

Claims, No.:

1-72 as originally filed

Drawings, sheets:

1-54 as originally filed

Sequence listing part of the description, pages:

1-12, as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☒ contained in the international application in written form.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

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EXAMINATION REPORT**International application No. **PCT/US99/30503**

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:
5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)
6. Additional observations, if necessary:

II. Priority

1. ☐ This report has been established as if no priority had been claimed due to the failure to furnish within the prescribed time limit the requested:
- ☐ copy of the earlier application whose priority has been claimed.
☐ translation of the earlier application whose priority has been claimed.
2. ☐ This report has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid.
- Thus for the purposes of this report, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:
see separate sheet

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application.
☒ claims Nos. 28,29,32-38,51,52,61,62.

because:

- ☒ the said international application, or the said claims Nos. 32-38,52,61,62 relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- ☐ the description, claims or drawings (*Indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

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☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 28,29,51.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | | |
|-------------------------------|------|--------|------------------------------|
| Novelty (N) | Yes: | Claims | 1-27,30-50,52-72 |
| | No: | Claims | |
| Inventive step (IS) | Yes: | Claims | 1-27,30-50,52-72 |
| | No: | Claims | |
| Industrial applicability (IA) | Yes: | Claims | 1-27,30,31,39-50,53-60,63-72 |
| | No: | Claims | |

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

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see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US99/30503

Re Item II**Priority**

Documents D1-D3 were published after the priority date of the present application. They do not, therefore, constitute part of the state of the art in the meaning of Rule 64(1)(b) PCT. Since the present application seems entitled to the priority date (22.12.98) claimed these documents will also not become relevant with respect to novelty and inventiveness in any regional phase.

However, since these documents claim priority dates earlier than that of the present application, they might become relevant under Art.54(3) and (4) EPC (see also Re Item VI).

Re Item III**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. No ISR has been established for the subject-matter of claims 28, 29 and 51. Therefore, these claims cannot be subjected to IPE.
2. Industrial applicability (Art.33(4) PCT)

Claims 32-38, 52, 61 and 62 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Art.34(4)(a)(i) PCT).

Re Item V**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: WO 99 47677 A (GENENTECH INC) 23 September 1999 (1999-09-23)
D2: WO 99 37671 A (NA SONGQING ;SONG HO YEONG (US); DOU

INTERNATIONAL PRELIMINARY

International application No. PCT/US99/30503

EXAMINATION REPORT - SEPARATE SHEET

SHENSHEN (US); LILLY CO ELI () 29 July 1999 (1999-07-29)

D3: EP-A-0 984 063 (LILLY CO ELI) 8 March 2000 (2000-03-08)

D4: WO 98 07832 A (UNIV HELSINKI LICENSING ;LUDWIG INST CANCER
RES (US)) 26 February 1998 (1998-02-26)

D5: WO 98 24811 A (ZYMOGENETICS INC) 11 June 1998 (1998-06-11)

2. Novelty (Art.33(2) PCT):

The prior art discloses various members of the VEGF family (see for example the description, page 1, line 21 to page 2, line 37, D4 which discloses VEGF-D, and D5 which discloses ZVEGF2). In contrast, the present application provides a novel member of this family, denominated VEGF-X and defined by its sequence according to claim 1, and/or by particular domains, such as the CUB domain according to claims 39-42 or the VEGF-like domain according to claim 43.

Accordingly, the subject-matter of the claims as far as subjected to IPE is novel.

3. Inventiveness (Art.33(3) PCT):

The novel member of the VEGF family is not rendered obvious by the cited prior art. Accordingly, the subject-matter of the claims as far as subjected to IPE also comprises an inventive step.

Re Item VI

Certain documents cited

Certain published documents (Rule 70.10)

| Application No | Publication date | Filing date | Priority date (valid claim) |
|------------------|------------------|-------------|-----------------------------|
| Patent No | | | |
| (day/month/year) | | | |
| (day/month/year) | | | |
| (day/month/year) | | | |

D1 WO9947677 23.09.99 10.03.99 17.03.98

02.11.98

D2 WO9937671

29.07.99

26.01.99

27.01.98

05.06.98

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/US99/30503

| | | | |
|----|---------------|----------|----------|
| | | | 24.06.98 |
| | | | 31.08.98 |
| D3 | EP-A-0 984063 | 08.03.00 | 16.07.99 |
| | | | 31.08.98 |

Re Item VII

Certain defects in the international application

Reference is made to claims 17, 18 and 65-67 which embrace human organism in their scope. This subject-matter is considered by the IPEA to be contrary to morality and are hence not allowable.

Re Item VIII

Certain observations on the international application

1. The term "functional equivalent" embraces structurally undefined proteins. In so far the claims referring to this feature do not meet the requirements of Art.6 PCT (lack of clarity).

In addition, and since other VEGF molecules share properties of the VEGF-X peptide of the present application, the scope of the claims thereby also embraces proteins which are not part of the present invention (Art.6 PCT, lack of support).

It is also noted that the claims referring to this feature seem to embrace prior art VEGFs and would therefore also not meet the requirements of Art.33(2) PCT.

2. The feature "bioprecursor" has not been defined either, neither in the claims nor in the description. Therefore, the skilled person is not in the position to exemplify such a precursor (Art.5 and Art.6 PCT).
3. Claims 32- 38, 52, 61 and 62 comprise the treatment of various diseases. However, there is no proof for the applicability claimed to be found in the description for any of these various applications. In the absence of such a proof the subject-matter of these claims appears rather speculative and cannot be considered to meet the requirements of Art.5 PCT.